# Scientific Review Board Charter

This charter defines the responsibilities of the Scientific Review Board (SRB), which is responsible for assessing and granting requests from qualified scientific and medical researchers for access to anonymized individual patient data (IPD) and redacted clinical study reports (CSRs) from clinical studies sponsored by Lundbeck or its development partners.

## Membership and Composition of the SRB

The SRB consists of four members with different areas of expertise to ensure a broad view on the research proposals. The composition will ensure that review and decisions can be taken on rigorous scientific grounds. At least one of the members must be a board-certified psychiatrist or neurologist and one must be a biostatistician.

The chair of the SRB is appointed by Lundbeck. Each member participates in a personal capacity, and does not represent any organization or institution with which he or she may be affiliated.

Members of the SRB are appointed for a minimum of 2 years. To ensure consistency and continuity, the aim is to begin to replace some SRB members on a rotating basis after the first 2 years. The membership of the SRB is on www.lundbeck.com\trials.

## Responsibility of the SRB

The purpose of the SRB is to review requests for access to IPD or CSRs from clinical studies sponsored by Lundbeck or its development partners and to decide whether to grant such requests. The SRB must determine that the IDP or CSRs are to be used for legitimate research addressing a scientific question that can help advance medical science or improve patient care and not for commercial reasons. If the SRB rejects a request, the SRB can advise a resubmission.

## Responsibility of Lundbeck

Lundbeck is responsible for ensuring that access to IPD or CSRs is only granted for research proposals that are within the scope of the patients' informed consent provided by the patients prior to their participation in the clinical study and that only anonymized (de-identified) IPD and redacted CSRs will be made available to researchers.

Lundbeck subject matter experts will assess the research proposal for completeness and whether it meets the requirements. For partnering projects, Lundbeck will perform the assessment together with the partner.

The SRB will receive all requests for access to IPD and CSRs, but only if the aspects of patient privacy can be secured will the research proposal be subject to the SRB's decision on access to the requested IPD or CSRs. If Lundbeck subject matter experts have assessed that the request for

IPD or CSRs cannot be delivered within the boundaries of the patients' informed consent or the IPD cannot be sufficiently anonymized, the SRB will receive a copy of the informed consent form, together with a clarification of the assessment made by Lundbeck.

If the SRB grants access to the IPD or CSRs, Lundbeck will prepare anonymized, individual patient-level datasets or redacted CSRs. If Lundbeck, for a particular request and despite its initial assessment, is not able to implement all reasonable steps to maintain anonymity, Lundbeck will not provide the IPD or CSRs. Lundbeck will inform the SRB accordingly. Lundbeck will inform the researcher of the issue and provide an explanation for the rejection.

It is the responsibility of Lundbeck to prepare and provide the IPD or CSRs. The expected timeline for this process is 60 working days from the date of the decision made by the SRB, provided that a signed Data Sharing Agreement is in place.

## Responsibility of the Secretariat

Lundbeck has established a secretariat to facilitate the day-to-day operations of the SRB. The responsibility of the secretariat includes technical review of requests for completeness, preparing the meetings and the review packages, and communication with researches on behalf of the SRB.

## Procedures for the SRB Meetings

The SRB will meet on a quarterly basis, with a possibility to meet face-to-face once yearly; the other three meetings will be web-based. At the meetings, the SRB will discuss the research proposals, and decide whether to grant access to the requested IPD or CSRs. All decisions on granting access will be publicly available on Lundbeck's corporate website www.Lundbeck.com\trials. The decision will be posted after the requesting researcher/research group has been informed of the decision.

The SRB will have access to a workspace hosting all documentation and correspondence with the researcher/research group for review. The documents will be accessible to the SRB members no later than 20 workings days before each meeting.

If no research proposals have been received for review by Lundbeck 30 working days prior to the next scheduled meeting, the meeting will be cancelled.

Lundbeck employees will participate in the meetings to provide administrative / technical assistance, but not be part of the decision by the SRB.

## Review Process and Requirements

During the review process, each member of the SRB will review the research proposals, diligently taking into account his or her own expertise.

The review criteria are:

- General (formal) assessment
- Patient's perspective

- Scientific perspective
- Methodology assessment

When deciding whether to grant access to the IPD or CSRs, the SRB must determine that the IPD or CSRs will only be used for addressing a relevant scientific question that can help advance medical science or improve patient care and not for commercial reasons.

During the review process, the SRB shall assess the following items:

1. Scientific objective: The research proposal must contain a research plan that explains the scientific rationale for the analysis and its relevance to medical research and/or patient outcomes.
2. Study design: The analytical methods and statistical analysis plan must be valid and support the proposed research in a coherent way with the ability to meet the scientific objectives.
3. Publication plan: The research proposal must contain a proposal for a publication plan demonstrating that the researcher/research group intends to publish the results of the study in a peer-reviewed scientific journal or otherwise make the results publically available.
4. Qualifications of the researchers: The researcher/research group must be qualified to perform the described analysis/study. The names and CVs of all members of the research group must be included in the proposal. At least one statistician (degree in statistics or a related discipline) shall be designated as part of the research group.
5. Conflicts of interest: Any real or potential conflicts of interest must be disclosed, as this could have an impact on the conduct or interpretation of the research.

## Decision-making Process

As a general rule, decisions of the SRB will be made by consensus. If it is not possible to reach consensus, the Chairman makes the final decision.

SRB members who are prevented from attending a meeting are required to submit their recommendation to the Chair no later than 2 working days before the meeting. The decisions will be prepared in writing by the Chair. Following agreement by all SRB members, the Chair forwards the signed decision paper to the secretariat within 7 working days after the meeting. The decision of the SRB will be communicated by the secretariat to the researchers.

## Compensation

Members of the SRB are compensated for their time and expertise. Compensation follows the Lundbeck standards for compensation of external advisors (fair market value) and disclosure follows the health-care professional (HCP) transparency regulations, when applicable. In addition, Lundbeck covers the costs for travel, accommodation and meals in connection with the SRB meetings.